

WSA 2003 Proposed Project

Project Name:	Influence of Smoking the EHCSS ACCORD® K3/K6 Puff Activated Lighter™ on Endothelium-Dependent Venoreactivity																					
Brief Description of Project:	<p>Assessment whether and to which extent endothelium-dependent venoreactivity is influenced by smoking conventional cigarettes, PREPs, or no-smoking and can be assessed non-invasively. A positive result will qualify the method for risk and harm reduction trials.</p> <p>Smokers of conventional cigarettes will be forced to switch to EHCSS ACCORD K3/K6 and to no smoking in a crossover design (Study duration 3 weeks/individual).</p>																					
Type of Deliverable(s):	<input checked="" type="checkbox"/> Assay <input checked="" type="checkbox"/> Knowledge																					
Reason for Doing this Work:	<input type="checkbox"/> Product Development Guidance <input checked="" type="checkbox"/> Product Evaluation	<input checked="" type="checkbox"/> Short Term <input type="checkbox"/> Long Term																				
Program Area: (Check all areas that apply)	<input type="checkbox"/> Cancer <input checked="" type="checkbox"/> CVD <input type="checkbox"/> COPD <input type="checkbox"/> Repro <input type="checkbox"/> ETS <input type="checkbox"/> Determinants of Smoke Exposure <input type="checkbox"/> Product Design Guidance <input type="checkbox"/> PI Specific Projects <input type="checkbox"/> CE Specific Projects <input type="checkbox"/> Sensory Specific Projects <input type="checkbox"/> Scientific Affairs & Communication Specific Projects <input type="checkbox"/> WSA PMI Specific Projects (Neuchatel & Asia) <input type="checkbox"/> PMRL Specific Projects (Germany & Belgium)																					
Project Leader:	Martin Unverdorben																					
Prioritization:	<input checked="" type="checkbox"/> Critical <input type="checkbox"/> Priority <input type="checkbox"/> Secondary <input type="checkbox"/> Low																					
Milestones: <p>The timelines are subject to approval of EHCSS by the German Authorities.</p> <table> <tr> <td>Final Protocol</td> <td>March 2003</td> </tr> <tr> <td>Venoreactivity Tests</td> <td>Sept.03</td> </tr> <tr> <td>Lab Analysis</td> <td>May04</td> </tr> <tr> <td>Data Evaluation</td> <td>June2004</td> </tr> <tr> <td>Draft Report</td> <td>July 2004</td> </tr> <tr> <td>Abstract</td> <td>September 2004</td> </tr> <tr> <td>Draft Manuscript</td> <td>October 2004</td> </tr> <tr> <td></td> <td>November</td> </tr> <tr> <td></td> <td>2004</td> </tr> <tr> <td></td> <td>December 2004</td> </tr> </table>		Final Protocol	March 2003	Venoreactivity Tests	Sept.03	Lab Analysis	May04	Data Evaluation	June2004	Draft Report	July 2004	Abstract	September 2004	Draft Manuscript	October 2004		November		2004		December 2004	Target Date:
Final Protocol	March 2003																					
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Internal Resource Allocation (WSA, PMRL, PMI) (Man Hours)		External Resource Allocation (other PMUSA, external vendors) (Man Hours)																				
WSA, PMUISA		Conduct of Study by Prof. Dr. W.Haefeli, University of Heidelberg																				

TO BE FILLED OUT BY WSA MANAGEMENT

- Approved as Written
- Approved with Modifications
- Not Approved

Reason

Signature of Coordinator (Date)

(Date)

Signature of Project Leader's Functional Director (Date)